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A multicenter randomised study comparing the efficacy of adefovir dipivoxil versus pegylated interferon alpha-2a plus placebo versus adefovir dipivoxil plus peglyated interferon alpha-2a for the treatment of chronic delta hepatitis

Submission date	Recruitment status	[_] Prospectively registered
03/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2011	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

Study information

Scientific Title

Acronym
Delta Study

Study objectives
Peg-interferon alpha-2a or adefovir lead to sustained virological response in 20-40% of the cases in chronic delta hepatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adults with chronic delta hepatitis

Interventions
A: Adefovir dipivoxil, 10 mg, orally (po) for 48 weeks
versus
B: Pegylated interferon alpha-2a, 180 µg subcutaneously (sc), plus placebo for 48 weeks
versus
C: Pegylated interferon alpha-2a, 180 µg sc, plus adefovir dipivoxil, 10 mg po for 48 weeks; biopsy at the end of treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Peg-interferon alpha-2a, adefovir dipivoxil

Primary outcome(s)

Response rate of normal ALT and HDV RNA negativity at the end of treatment (ETR)

Key secondary outcome(s))
1. Response rate of normal ALT and HDV RNA negativity at the end of follow-up (EOF)
2. Suppression of hepatitis B virus (HBV) DNA below 1x10^5 copies/ml at ETR and EOF
3. Paired biopsy comparison
4. HBsAg levels, loss of HBsAg and HBs Antibodies at ETR and EOF
5. HBV and HDV specific T cell response
6. Saftey (adverse events, vital signs, clinical laboratory parameters)

Completion date
01/10/2004

Eligibility

Key inclusion criteria
1. Age >18 years
2. Positive Hepatits B surface Antigen (HBsAg)
3. Positive anti-hepatitis D virus (HDV) antibodies
4. Positive HDV-Ribonucleic Acid (RNA) by Polymerase Chain Reaction (PCR)
5. Serum alanine aminotransferase (ALT) >upper limit of normal (ULN) but <10 x ULN
6. Liver biopsy demonstrating liver disease consistent with chronic heaptitis
7. Liver imaging for patients with cirrhosis or marked fibrosis to rule out hepatic carcinoma
8. Negative urine or serum pregnancy test
9. Willingness to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Antiviral therapy in previous six months
2. Positive tests for hepatitis A virus (HAV) Immunoglobulin M (IgM) antibodies, hepatitis C virus (HCV) RNA or HCV antibodies or Human Immunodeficiency Virus (HIV) antibodies
3. Serum total bilirubin >2 x ULN
4. Decompensated liver disease Child B-C
5. Other reasons for chronic liver disease
6. Haemoglobin <11.5 g/dl for females and <12.5 g/dl for males
7. White blood cell count (WBC) <3000 cells/mm^3

8. Serum creatinine >1.5 x ULN
9. Relevant psychiatric diseases
10. Drug or alcohol abuse within one year of entry
11. Other evidence or histroy of severe illness
12. Thyroid disease poorly controlled
13. Alphafetoprotein (AFP) >100 ng/ml

Date of first enrolment
01/04/2004

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
Germany

Study participating centre
Medizinische Hochschule Hannover
Hannover
Germany
30625

Sponsor information

Organisation
Hannover Medical School (MHH) (Germany)

ROR
https://ror.org/00f2yqf98

Funder(s)

Funder type
University/education

Funder Name
Network of competence for hepatitis (Kompetenznetz Hepatitis [Hep-Net e.V.]), c/o Hannover Medical School (Medizinische Hochschule Hannover [MHH]) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/01/2011		Yes	No